Issue Summary
Blood Products Advisory Committee
December 11-12, 2003

Topic: American Association for Blood Banks (AABB) Abbreviated Questionnaire

Issue: The AABB Uniform Donor History Task Force has submitted to FDA a revised Uniform Donor History Questionnaire (UDHQ) donor screening process, which includes a full-length donor-screening questionnaire and related materials, as well as an abbreviated questionnaire format for use by frequent repeat donors. At this time, FDA seeks the Committee's recommendations regarding several unresolved aspects of the proposed abbreviated questionnaire procedures. These include:

1. Assessment of the extent to which existing data demonstrate that the risk: benefit of the UDHQ abbreviated questionnaire is at least equivalent to current donor screening instruments either in its proposed format, or as a pilot program.
2. Consideration of strategies for pilot implementation of abbreviated questionnaires in a regulated environment that would produce data relevant to routine implementation.

Background:
The concept of an abbreviated blood donor screening questionnaire for repeat blood donors has been discussed for many years as a means to reduce donor and staff frustration with the repeated collection of the same information at every donation appearance. The abbreviated questionnaire is designed to combine the collection of new eligibility information that may have changed from the time of the previous donation with baseline information that is captured in the extant donor record. Thus, donor characteristics that do not change (demographics, and medical/behavioral history information documented from previous donations) are generally not re-ascertained, while relevant changes that occurred since the previous donation are captured by interval-defined questions. The abbreviated questionnaire format is only available for established repeat blood donors, who maintain a pattern of regular donation as defined in the blood center standard operating procedures.

The concept was first proposed and discussed formally as part of the FDA-sponsored study of the donor screening process conducted by the American Institutes for Research in the early 1990's. At that time, industry reaction to the possibility of an abbreviated screening process for repeat donors was muted by the absence of comprehensive on-site computer databases that would allow error-free identification of repeat donors who met eligibility requirements for the procedure defined by the collection establishment's SOP. In recent years, the capability of on-site computer systems has improved, permitting more reliable identification of repeat donors eligible for an abbreviated questionnaire.

While available data comparing the prevalence of infectious disease markers in first time donors vs. the general public support the added value of the donor screening process in general, neither the full-length donor questionnaire nor the abbreviated questionnaire format has been formally validated for their ultimate impact on blood safety. Such studies have not been possible due to the difficulties of conducting a clinical trial of different donor screening

procedures in a regulated environment and the extremely low rate of recognized post-transfusion negative outcomes.

It has been argued that there may be a loss of predictive value related to donor safety in not repeating key risk questions at each donation attempt. This concern is compatible with data compiled from blood product deviation reports to FDA showing that corrections to donor eligibility information made available to the blood center after blood collection (post-donation information, or PDI) may continue to be received at the third repeat donation and beyond.

Conversely, others (including behavioral scientists knowledgeable in blood collection procedures) consider the ability of an abbreviated questionnaire to specifically focus donor attention on recent time periods (e.g. window-period infection) as a major advantage. It has also been argued, again on a theoretical basis, that the depth of attention and response of subjects to a questionnaire is highly dependent on the degree of relevance that the subject attributes to the questions being asked, i.e. donors may self-defer with improved accuracy if queries are narrowed to only include important information that may have recently changed.

At the September 23, 1993 meeting of the Blood Products Advisory Committee the results of the AIR study including use of an abbreviated questionnaire format were discussed. At this meeting the Committee recommended to FDA that information from the AIR study was not sufficient to demonstrate equivalence of an abbreviated history for repeat donors. (Yes – 0, No – 6, Abstain – 1). Subsequently, on March 25, 1994 the BPAC again discussed the final report of the AIR Study and (without vote) a majority of members indicated in their comments that while the AIR study had not produced data showing equivalence of the abbreviated questionnaire format, the use of the abbreviated form appeared to be a favorable development. The issue was again discussed at a October 16, 2000 FDA-sponsored workshop on Streamlining the Donor History Questionnaire at which time FDA voiced support for streamlining of the donor screening process, but expressed concerns about the reliability of selecting donors eligible for the abbreviated procedure and a possible increase in blood collection errors.

Over the past twelve years, an abbreviated questionnaire process has been developed and implemented across the source plasma industry. This process includes annual re-administration of the full-length questionnaire.

A small number of whole blood collection establishments have submitted prior-approval license amendments for implementation of an abbreviated questionnaire format. The first such approval, in 1998, was for use of an abbreviated questionnaire for repeat whole blood donors who meet specified criteria, as well as for RBC and platelet apheresis donors. An additional approval expanded use of an abbreviated procedure to nineteen additional blood centers, representing approximately 15% of the total US Blood supply

The Committee will hear presentations from FDA regarding the background and regulatory perspective of abbreviated donor questionnaires and general considerations about the predictive value of the donor screening process. . The AABB will present the design and

rationale of its proposed UDHQ abbreviated questionnaire procedure followed by FDA's specific review comments. Finally, two blood establishments currently using abbreviated formats will present their experiences and a survey design specialist from The National Center for Health Statistics and will discuss available risk benefit considerations of abbreviated questionnaire design from a behavioral perspective.

Questions for the Committee

1. Do current data support the use of the AABB UDHQ abbreviated questionnaire as equivalent to the current donor screening process? Y N

2. If not, does the committee believe that current data support approval of pilot programs to evaluate performance of an abbreviated donor questionnaire in a regulated blood collection environment? Y N

2a. If so, please comment on the design of pilot studies (e.g. pilot re-administration of the full-length questionnaire annually to repeat donors and consideration of conversion to biennial administration based upon submitted data.)

2b. If not, what additional data are needed prior to approval of an abbreviated donor questionnaire pilot program in a regulated blood collection environment.